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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,035	02/05/2004	Teodzyj Kolasa	7283.US.01	6968

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EXAMINER
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BERNHARDT, EMILY B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/773,035

Applicant(s)

KOLASA ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40,42-63 and 65-96 is/are pending in the application.
- 4a) Of the above claim(s) 12-17,21-31,39,49-52,55-62 and 70-96 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,6-10,18 and 19 is/are allowed.
- 6) ☒ Claim(s) 2,5,32-38,40,42-48,53,54,63,65-69 is/are rejected.
- 7) ☒ Claim(s) 11 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Applicant's election without traverse of I in the reply filed on 7/13/06 is acknowledged. It is noted that nonelected claims are still pending. Only claims 39 and 70 could be theoretically rejoined under the Rejoinder Practice and only if examined prior to a FINAL rejection.

The Abstract remains objected to. As stated in the MPEP 608.01(b), Section B: "With regard particularly to chemical patents, for compounds or compositions, the general nature of the compound or composition should be given as well as the use thereof, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." **Exemplification of a species** could be illustrative of members of the class." . It is suggested a species be identified by way of name or formula to more clearly inform the public of the chemical makeup of applicants' compounds.

Applicants' amendments overcomes most of the 112 rejections set forth in the previous action. However the following rejections apply.

Claims 33-36,38,40,42-48,53,54,65-67 and 69 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating male erectile dysfunction (MED), does not reasonably provide enablement for the treatment of all forms of male and female sexual dysfunction (SD) of which

there are many types and possible mechanism of action. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicants appear to be disparaging the references of record because they do not address other types of SD just MED. This is not quite true as Melis, ref. C11, cited by applicants states in the abstract: "...no conclusion can be deduced from the available studies on the role of central dopaminergic systems in the control of proceptivity and receptivity, the two main components of female sexual behavior." The purpose of review articles such as those cited by applicants is to inform one what is within the level of skill in a particular art- rather what is not. Indeed, priapism, an opposite condition to MED, has been stated in an online publication available at ([www.leaddiscovery.co.uk/dossiers/MDI002/Sexual%20dysfunction.htm](http://www.leaddiscovery.co.uk/dossiers/MDI002/Sexual%20dysfunction.htm)) "to be poorly understood "- see section entitled "Male sexual dysfunction". In the same online publication is a table of drugs in clinical trials for a variety of disorders including SD. While some of these are D agonists, they are indicated for MED and not female dysfunction as embraced herein nor for priapism also embraced herein. Thus, there is much evidence to question the efficacy of the scope of uses covered by the method claims .

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buzas (GB'523) in view of Buzas (GB'080). Both references have been cited by applicants. The compound previously pointed out as anticipatory is in fact a higher homolog having a C# chain in place of instant C1 or C2 chain as noted by applicants. However the species in claim 5 previously pointed out by the examiner remain obvious variants. Contrary to what applicants state Buzas (GB'080) teaches for similar compounds and use to that in the primary reference that the carbon length corresponding to instant "L" can be C1-C3 and that alkyl groups can be present on the oxime O. Thus there is ample motivation to modify the closest compound taught in the primary reference by changing the carbon length at "L" as well as modifying the allyl with lower alkyl. The fact that a different use is taught is irrelevant when rejecting compound/composition claims. Applicants must show that their compound(s) possess a property that the prior art compound(s) do not possess- not is not disclosed to possess. See *In re Best* 195 USPQ 430; *In re Dillon* 16 USPQ 2d 1897.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yevich. Yevich, newly cited also describes a compound very similar to some of the

species in claim 5 for use as D2 antagonists for treating schizophrenia. See compound 32 in Table I. Said compound differs only in being a higher homolog at instant "L" from pyrimidinyl species in claim 5 on p.4 ,12<sup>th</sup> and 13<sup>th</sup> species. Compounds that differ by number of CH<sub>2</sub> chains are not considered patentably distinct absent evidence of superior, unexpected results. Note for example, Ex parte Ruddy 121 USPQ 427; Ex parte Nathan 121 USPQ 349; In re Shetty 195 USPQ 753 regarding the patentability of homologs. Thus it would have been obvious to one skilled in the art at the time the invention was made to expect instant ethanone oxime analogs of Yevitch's compound to be also useful as antipsychotics in view of the close structural similarity outlined above.

Generic claims 1-4, etc. are not rejected in the above art rejections as it is noted applicants have amended the generic claims at R<sub>B</sub> excluding hydrogen as a choice and thus the prior art is further removed from the generic scope. However, the following claims are now improperly dependent on claim 1.

Claims 5, 11, 20 and 44 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 5, 11, 20 and 44 contain many if not all of the species

outside the scope of claim 1 which no longer permits piperazino carbons to be unsubstituted. Additionally, it is noted that claim 11 which directly depends on claim 4 is outside the scope of that claim as well which requires that R2 be aryl while species in 11 is heteroaryl.

Claims 2, 32-38 and 40,63,65-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Various pairs of these claims appear to be duplicates as far as the examiner can determine. If applicants disagree they need to point out where a material difference exists. See 32 v 63 and 33 v 40 and 34 v 65 and 35 v 66 and 36 v 67 and 37 v 68 and 38 v 69.

2. Claim 2 is not seen to be further limiting the scope of claim 1 in view of the deletion of nonelected subject matter in claim 1. Thus the claim should be cancelled.

Claims 1,3,4,6-10 and 18-19 are allowed.

Claims 11 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Emily Bernhardt  
Primary Examiner  
Art Unit 1624